

UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

FILED

APR 24 2006 

Phil Lombardi, Clerk
U.S. DISTRICT COURT

UNITED STATES OF AMERICA,

Plaintiff-Counter-
Defendant - Appellant,

v.

RX DEPOT, INC., corporation; RX OF
CANADA, LLC., corporation; CARL
MOORE, individual; DAVID PEOPLES,
individual,

Defendants-Counter-
Claimants - Appellees,

WASHINGTON LEGAL
FOUNDATION,

Amicus Curiae.

No. 05-5003

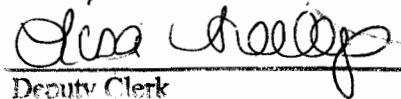
03-CV-616-CVE ✓

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Teste

Clerk, U. S. Court of
Appeals, Tenth Circuit

By


Deputy Clerk

JUDGMENT

Filed February 22, 2006

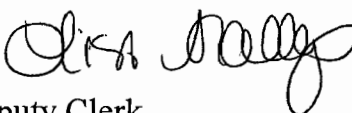
Before **HENRY, McWILLIAMS AND MURPHY**, Circuit Judges.

This case originated in the Norther District of Oklahoma and was argued by counsel.

The judgment of that court is reversed. The case is remanded to the United States

District Court for the Northern District of Oklahoma for further proceedings in accordance with the opinion of this court.

Entered for the Court
ELISABETH A. SHUMAKER, Clerk

by: 
Deputy Clerk

FILED
United States Court of Appeals
Tenth Circuit

PUBLISH

February 22, 2006

UNITED STATES COURT OF APPEALS

Elisabeth A. Shumaker
Clerk of Court

TENTH CIRCUIT

UNITED STATES OF AMERICA,

Plaintiff-Counter-
Defendant-Appellant,

v.

RX DEPOT, INC., corporation; RX OF
CANADA, LLC, corporation; CARL
MOORE, individual; DAVID
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No. 05-5003

Defendants-Counter-
Claimants-Appellees.

WASHINGTON LEGAL
FOUNDATION,

Amicus Curiae.

**Appeal from the United States District Court
for the Northern District of Oklahoma
(D.C. No. CV-03-616-EA(M))**

Mark Reiling Freeman, Appellate Staff, Civil Division, U.S. Department of Justice (Peter D. Keisler, Assistant Attorney General, David E. O'Meilia, United States Attorney, Scott R. McIntosh, Appellate Staff, Civil Division, U.S. Department of Justice, Alex M. Azar II, General Counsel, Sheldon T. Bradshaw, Chief Counsel, Food and Drug Division, Gerald F. Masoudi, Acting Chief

Counsel, Food and Drug Division, Eric M. Blumberg, Deputy Chief Counsel, Litigation, Michael M. Levy, Associate Chief Counsel for Enforcement, United States Department of Health and Human Services, Office of the General Counsel, Of Counsel, with him on the briefs), Washington, D.C., for Plaintiff-Counter-Defendant-Appellant.

Fred E. Stoops, Sr. (E. Diane Hinkle, with him on the brief), Tulsa, Oklahoma, for Defendants-Counter-Claimants-Appellees.

Daniel J. Popeo, Richard A. Samp, Counsel of Record, Washington Legal Foundation, Washington, D.C., filed an amicus curiae brief on behalf of Defendants-Counter-Claimants-Appellees.

Before **HENRY, McWILLIAMS** and **MURPHY**, Circuit Judges.

MURPHY, Circuit Judge.

I. Introduction

Appellees Rx Depot, Inc., Rx of Canada, LLC, Carl Moore, and David Peoples (collectively “Rx Depot”) facilitated the sale of prescription drugs from Canada to customers in the United States. The United States brought suit against Rx Depot, alleging its business practices violated provisions of the Federal Food, Drug and Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301–397. Rx Depot admitted to violating the Act and entered into a consent decree of permanent injunction. Subsequently, the United States sought disgorgement of Rx Depot’s profits. The district court denied disgorgement, concluding it was not an available remedy under the FDCA as a matter of law. We exercise jurisdiction pursuant to 28

U.S.C. § 1291. Because the FDCA invokes courts' general equity jurisdiction and does not prohibit disgorgement by clear legislative command or necessary and inescapable inference, we **reverse** and **remand**.

II. Background

Rx Depot helped consumers in the United States obtain prescription drugs from Canada at reduced prices. A customer with a prescription from an American physician could download forms from Rx Depot's website or visit one of Rx Depot's storefront affiliates to order medications. Rx Depot then transmitted the customer's forms, prescription, and payment information to cooperating Canadian pharmacies. A Canadian physician would rewrite the prescription, which was then filled by a Canadian pharmacy and sent directly to the customer in the United States. Rx Depot received a ten to twelve percent commission for each sale they facilitated.

The United States filed a civil action alleging Rx Depot's activities violated provisions of the FDCA. Specifically, the Government alleged Rx Depot violated § 381(d)(1) by reimporting prescription drugs originally manufactured in the United States and § 355(a) by introducing new drugs into interstate commerce without FDA approval. The government sought a temporary and permanent injunction and other equitable relief. The district court entered a preliminary injunction ordering Rx Depot to discontinue its business activities. The parties then agreed to, and the district court approved, a consent decree of permanent

injunction. In the consent decree, Rx Depot admitted to violating the FDCA and agreed not to resume its business operations. The consent decree left “to the discretion of [the district court] the issue of what, if any, equitable relief, including restitution and/or disgorgement, should be awarded to [the United States].”

Subsequently, the district court denied restitution, reasoning Rx Depot’s customers did not lose money in their transactions because they purchased medications at reduced prices. The district court initially concluded disgorgement would be an appropriate remedy. Upon reconsideration, however, the district court determined disgorgement was not available under the FDCA as a matter of law. Although the FDCA invokes courts’ equity jurisdiction, the district court determined the Act’s express provision of other remedies and legislative history create a necessary and inescapable inference that Congress intended to restrict courts’ power to order disgorgement. The United States appeals only the district court’s denial of disgorgement.

III. Discussion

We review questions of statutory interpretation *de novo*. *Employers Reinsurance Corp. v. Mid-Continent Cas. Co.*, 358 F.3d 757, 774 (10th Cir. 2004). The FDCA provides, “[t]he district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown to restrain violations of [the FDCA].” 21 U.S.C. § 332(a). The issue before this

court is whether this statutory grant of jurisdiction enables district courts to order disgorgement in appropriate cases.

In *Porter v. Warner Holding Co.*, the Supreme Court held when Congress invokes the equity jurisdiction of courts in a statute, “all the inherent equitable powers of the [courts] are available for the proper and complete exercise of that jurisdiction,” unless the statute, by “clear and valid legislative command” or “necessary and inescapable inference,” restricts the forms of equitable relief authorized. 328 U.S. 395, 398 (1946). The Court in *Porter* was examining whether § 205(a) of the Emergency Price Control Act of 1942 (“EPCA”)¹ permitted federal courts to order restitution of rents collected in excess of statutory maximums. *Id.* at 396. The Court determined restitution was authorized by the statute because § 205(a) invoked courts’ general equity jurisdiction and the statute did not expressly or impliedly preclude restitution. *Id.* at 397–98, 403. Moreover, the Court noted because the suit involved the public interest and not merely a private controversy, courts’ “equitable powers assume[d] an even broader and more flexible character.” *Id.* at 398.

¹Section 205(a) provided:

[T]he Administrator [of the Office of Price Administration] may make application to the appropriate court for an order enjoining . . . acts or practices [in violation of the statute] . . . and upon a showing by the Administrator . . . [of] such acts or practices a permanent or temporary injunction, restraining order, or other order shall be granted without bond.

Emergency Price Control Act of 1942, § 205(a), 56 Stat. 23, 33.

Arguably, the Court's decision in *Porter* also relied in part on the broad language of § 205(a), which authorized "any . . . other order." *See id.* at 399. The Court's subsequent decision in *Mitchell v. Robert De Mario Jewelry, Inc.*, however, demonstrates that such inclusive language is not required. 361 U.S. 288, 291 (1960); *see also Atchison, Topeka and Santa Fe Ry. Co. v. Lennen*, 732 F.2d 1495, 1506 (10th Cir. 1984). In *Mitchell*, the Court determined the Fair Labor Standards Act ("FLSA") authorizes federal courts to order reimbursement of lost wages to employees who are discriminated against or unlawfully discharged for filing complaints under the Act. *Id.* at 296. The Court relied exclusively on language in the statute granting courts authority "for cause shown, to restrain violations of [the FLSA]." *Id.* at 289, 291. The Court observed that the absence of language in the statute affirmatively confirming the power of courts to order reimbursement did not preclude such relief in light of the statute's grant of general equity jurisdiction. *Id.* at 291. The Court explained, "[w]hen Congress entrusts to an equity court the enforcement of prohibitions contained in a regulatory enactment, it must be taken to have acted cognizant of the historic power of equity to provide complete relief in the light of statutory purposes." *Id.* at 291–92. Accordingly, under *Porter* and *Mitchell*, when a statute invokes general equity jurisdiction, courts are permitted to utilize any equitable remedy to further the purposes of the statute absent a clear legislative command or necessary and inescapable inference restricting the remedies available.

Amicus argues our analysis of the remedies available under the FDCA should be guided by *Meghrig v. KFC Western, Inc.* instead of *Porter* and *Mitchell*. *Meghrig*, 516 U.S. 479 (1996). *Meghrig* held the grant of general equity jurisdiction in the Resource Conservation and Recovery Act's ("RCRA") citizen suit provision² does not authorize courts to order restitution of past cleanup costs. *Id.* at 487. The plaintiff in *Meghrig* owned property contaminated with petroleum products. *Id.* at 481. After having the waste removed and disposed of, the plaintiff brought suit against a former property owner seeking recovery of cleanup costs the plaintiff had expended. *Id.* at 481–82. In concluding the remedy was not available under RCRA, the Court recognized, but did not overrule, *Porter*'s and *Mitchell*'s holding that a statutory grant of general equity jurisdiction authorizes courts to use all traditional equitable powers. *Id.* at 487; *see also United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 496 (2001) (citing *Porter* in a case decided after *Meghrig* for the proposition that courts sitting in equity "have discretion unless a statute clearly provides otherwise"); *Miller v. French*, 530 U.S. 327, 340–41 (2000) (same). Instead, the Court merely identified RCRA as a statute that fit into the exceptions recognized by *Porter* and *Mitchell*. *Meghrig*, 516 U.S. at 487. In particular, the Court determined RCRA

²RCRA's citizen suit provision authorizes district courts "to restrain any person who has contributed or who is contributing to the past or present handling, storage, treatment, transportation, or disposal of any solid or hazardous waste . . . , to order such person to take such other action as may be necessary, or both . . ." 42 U.S.C. § 6972(a).

contained a clear legislative command and concluded Congress did not intend to permit recovery of past cleanup costs. *Id.* at 484–88. The Court also determined the recovery of past cleanup costs was not consistent with the statutory purposes of RCRA. *Id.* at 483.

First, the Court reasoned the clear language of RCRA’s citizen suit provision precludes an order of restitution for past cleanup costs. *Id.* at 486. RCRA’s citizen suit provision permits suit “against any person . . . who has contributed or who is contributing to the past or present handling, storage, treatment, transportation, or disposal of any solid or hazardous waste which may present an imminent and substantial endangerment to health or the environment . . .” 42 U.S.C. § 6972(a)(1)(B). The Court observed that the requirement that waste “*may present an imminent . . . endangerment*” demonstrated the provision was directed only at harm that threatens to occur in the immediate future. *Meghrig*, 516 U.S. at 485–86 (emphasis added). Thus, it concluded, costs for the *past* cleanup of waste that no longer poses a danger to health or the environment are not recoverable. *Id.*

Second, the Court found evidence that Congress did not intend to authorize restitution of past cleanup costs in both the structure of RCRA and its relation to another environmental statute. RCRA prohibits citizen suits when either the EPA or the State has commenced a separate enforcement action. 42 U.S.C. § 6972(b)(2)(B) & (C). Thus, if RCRA permitted restitution for past cleanup costs,

it would only provide compensation in those cases in which waste problems are not severe or substantial enough to attract governmental attention. *Meghrig*, 516 U.S. at 486–87. The Court rejected this result as wholly irrational, concluding Congress could not have intended to provide compensation for individuals with minor waste problems while leaving individuals with severe or substantial waste problems without a remedy. *Id.*

The Court’s analysis also relied on significant differences between RCRA and the Comprehensive Environmental Response, Compensation, and Liability Act (“CERCLA”). CERCLA, which was enacted several years after RCRA, contains a citizen suit provision which mimics RCRA’s and authorizes courts “to order such action as may be necessary to correct” violations of the Act. *Id.* at 485. Unlike RCRA, however, CERCLA also contains an explicit provision permitting the recovery of remediation costs. *Id.* (citing 42 U.S.C. § 9607(a)(4)(B)). The Court concluded the absence of similar language in RCRA compelled an inference that Congress did not intend to provide past cleanup costs under RCRA because it would have been unnecessary for Congress to specifically enumerate the remedy in CERCLA if it was already encompassed within the statute’s grant of general equity jurisdiction. *Id.* at 485, 487.

Finally, the Court noted an award of past cleanup costs is inconsistent with RCRA’s purposes. *Id.* at 483. The primary purposes of RCRA, according to the Court, are to reduce the generation of hazardous and solid waste and ensure its

proper treatment, storage, and disposal, not to effectuate the cleanup of waste sites or to compensate those who have remediated waste sites. *Id.*

Thus, rather than overruling or limiting *Porter*'s and *Mitchell*'s general rule that a grant of equity jurisdiction enables courts to order any form of equitable relief, *Meghrig* merely demonstrates that a statute's particular characteristics may preclude application of the rule. *See Meghrig*, 516 U.S. at 487. Additionally, *Meghrig* is distinguishable from the present case, and from *Porter* and *Mitchell*, because it involved a controversy between private parties relying on a statutory provision for private causes of action, not an enforcement action by the government to protect the public. As the Court pointed out in *Porter*, "equitable powers assume an even broader and more flexible character" in suits involving the public interest. 328 U.S. at 398. Thus, *Meghrig*'s restrictive view of the remedies available under RCRA's citizen suit provision is likely due in part to the private nature of actions brought under the provision. *See United States v. Price*, 688 F.2d 204, 213–14 (3d Cir. 1982) (observing that 42 U.S.C. § 6973, a RCRA provision which authorizes the EPA to bring suit to restrain violations of the Act, confers upon courts broad authority to grant equitable relief). For these reasons, the general rule announced in *Porter*, and followed by *Mitchell* and *Meghrig*, guides our analysis.³

³Amicus contends that by implying additional remedies in a statute where Congress authorized only specified forms of relief, *Mitchell* exemplifies the type of analysis the Supreme Court once employed in implying private rights of action.

Section 332(a) of the FDCA invokes the equity jurisdiction of courts using the same statutory language the Supreme Court construed in *Mitchell* to authorize all traditional equitable remedies. Compare 21 U.S.C. § 332(a) (“district courts . . . shall have jurisdiction, for cause shown to restrain violations”), with 29 U.S.C. § 217 (“district courts . . . shall have jurisdiction, for cause shown, to restrain violations”); see *Mitchell*, 361 U.S. at 289, 291–92. Disgorgement is a traditional

Amicus notes that the Supreme Court abandoned implying private rights of action in *Alexander v. Sandoval*, and argues the Court similarly abandoned implying equitable remedies in *Meghrig*. *Sandoval*, 532 U.S. 275 (2001); *Meghrig v. KFC Western, Inc.*, 516 U.S. 479 (1996). As discussed above, *Meghrig* did not overrule or limit *Porter* and *Mitchell*. *Mitchell v. Robert De Mario Jewelry, Inc.*, 361 U.S. 288 (1960); *Porter v. Warner Holding Co.*, 328 U.S. 395 (1946). To the extent amicus argues *Sandoval* should persuade this court that the reasoning of *Porter* and *Mitchell* have been abandoned by the Supreme Court, we disagree. The line of cases from *J.I. Case Co. v. Borak* to *Sandoval* discusses the circumstances in which courts should imply a right of action allowing private parties to sue to enforce a statute when the statute itself does not explicitly authorize any such action. *J.I. Case*, 377 U.S. 426, 431–33 (1964), *abrogated by Sandoval*, 532 U.S. 275 (implying private right of action because it effectuated the purpose of the statute); *Sandoval*, 532 U.S. at 293 (refusing to imply private right of action where there was no evidence Congress intended to provide one). These cases are not applicable here for two reasons. First, we are not being asked to imply a private right of action under the FDCA. Second, while the statutes at issue in *J.I. Case* and *Sandoval* did not explicitly authorize private rights of action, the FDCA, and the statutes at issue in *Porter*, *Mitchell*, and *Meghrig*, contain an explicit grant of general equity jurisdiction. Although that grant does not enumerate all available forms of equitable relief, a general grant of equity jurisdiction has long been recognized as authorizing courts to employ all their traditional equitable powers. See *Porter*, 328 U.S. at 398. Thus, there is a statutory anchor for the equitable remedies here that is not present in cases where private rights of action are implied. For these reasons, we decline amicus’ invitation to construe broadly the reasoning of *Sandoval* as overruling dissimilar, long-standing precedent. See *State Oil Co. v. Khan*, 522 U.S. 3, 20 (1997) (“it is th[e] [Supreme] Court’s prerogative alone to overrule one of its precedents”).

equitable remedy. *FTC v. Gem Merch. Corp.*, 87 F.3d 466, 469 (11th Cir. 1996). Moreover, because the present action was brought by the government to protect the public health and safety, courts' equitable jurisdiction under the statute "assume[s] an even broader and more flexible character." *Porter*, 328 U.S. at 398. Thus, disgorgement is available under the FDCA unless (1) there is a clear legislative command or necessary and inescapable inference prohibiting disgorgement or (2) disgorgement is inconsistent with the purposes of the FDCA.

Rx Depot and amicus first contend the text of the FDCA limits the remedies available under the Act to forward-looking remedies. They argue the term "restrain" in § 332(a) envisions stopping ongoing violations of the Act or preventing future ones, not punishing past violations. Thus, they urge, the backward-looking remedy of disgorgement is expressly prohibited by the statute.

In *Mitchell*, the Supreme Court interpreted the statutory command "to restrain violations" to permit the arguably backward-looking remedy of restitution. 361 U.S. at 296; *see also Atchison*, 732 F.2d at 1506–07.

Subsequently, in *Meghrig*, the Court observed that the term "restrain" in RCRA envisions forward-looking, prohibitory injunctions. 516 U.S. at 484. In that case, however, the Court also relied heavily on other language expressed and implied in the statute in concluding restitution of past cleanup costs was not available. *See id.* at 483–87. Moreover, the Court did not explicitly overrule *Mitchell*'s holding that backward-looking remedies are permitted under a grant of authority to

restrain violations. In light of these considerations, we do not think the presence of the term “restrain” in a statutory grant of general equity jurisdiction is dispositive evidence of Congress’s intent to limit remedies to those that are forward-looking.⁴

Rx Depot and amicus also rely on *United States v. Philip Morris USA, Inc.* in arguing that a statutory grant of equity jurisdiction “to restrain violations” authorizes only forward-looking remedies. 396 F.3d 1190 (D.C. Cir. 2005). In *Philip Morris*, a divided panel of the District of Columbia Circuit held disgorgement was not available under the Racketeer Influenced and Corrupt Organizations Act (“RICO”), 18 U.S.C. §§ 1961–68. *Id.* at 1202. RICO authorizes district courts

to prevent and restrain violations of [RICO] by issuing appropriate orders, including, but not limited to: ordering any person to divest himself of any interest, direct or indirect, in any enterprise; imposing reasonable restrictions on the future activities or investments of any person . . . ; or ordering dissolution or reorganization of any enterprise

⁴It is not clear that disgorgement is solely a backward-looking remedy. One purpose of disgorgement is to deter future violations of the law by making illegal conduct unprofitable. *See Porter*, 328 U.S. at 400. When disgorgement is ordered to prevent future violations of the law it is a forward-looking remedy. *See e.g., SEC v. First Jersey Sec., Inc.*, 101 F.3d 1450, 1475 (2d Cir. 1996) (noting primary purpose of disgorgement under federal securities laws is forward-looking deterrence); *United States v. Carson*, 52 F.3d 1173, 1182 (2d Cir. 1995) (observing that disgorgement of recently acquired profits may serve forward-looking purpose of preventing future violations); *cf. United States v. Lane Labs-USA Inc.*, 427 F.3d 219, 229 (3d Cir. 2005) (noting restitution is forward-looking because it can serve deterrent function).

18 U.S.C. § 1964(a). Citing *Meghrig*, the court reasoned the statutory language “to prevent and restrain” limited courts to ordering forward-looking remedies aimed at preventing future violations of the Act. *Id.* at 1199. *But see id.* at 1220–22 (Tatel, J., dissenting) (arguing that *Porter* and *Mitchell*, not *Meghrig*, control). The court also relied on the fact that the remedies enumerated in the statute’s jurisdictional grant are all forward-looking. Thus, the court applied the canons *noscitur a sociis* and *ejusdem generis* to conclude that any authorized remedies beyond those specifically mentioned in the statute must be similarly forward-looking. *Id.* at 1200. *But see id.* at 1224 (Tatel, J., dissenting) (questioning the applicability of the canons in light of the statute’s command that the list of remedies is not exhaustive).

Although we express no opinion regarding whether, or in what circumstances, disgorgement is authorized under RICO, *Philip Morris* is inapposite to our decision here because the court relied on statutory language in RICO not present in the FDCA. *See id.* at 1199 (“In the RICO Act, Congress provided a statute granting jurisdiction defined with the sort of limitations not present in the FLSA or the EPCA.”). In any event, we note that *Philip Morris* did not question the continued validity of *Porter* and *Mitchell*, the cases we rely on here. *See id.* at 1200 (ruling out disgorgement remedy using *Porter* test).⁵

⁵Two other circuits have concluded RICO does not categorically prohibit disgorgement. *See Richard v. Hoechst Celanese Chem. Group, Inc.*, 355 F.3d 345, 354–55 (5th Cir. 2003); *Carson*, 52 F.3d at 1181. In both cases, however,

Rx Depot and amicus next contend that because the FDCA explicitly authorizes certain remedies, we should be reluctant to infer additional remedies. Defendants and amicus fail to recognize that by granting courts general equity jurisdiction, Congress authorized all traditional equitable remedies. As the Court noted in *Mitchell*, “[w]hen Congress entrusts to an equity court the enforcement of prohibitions contained in a regulatory enactment, it must be taken to have acted cognizant of the historic power of equity to provide complete relief in the light of statutory purposes.” 361 U.S. at 291–92. Thus, we need not infer any remedies; rather, all equitable remedies are available unless Congress’s express provision of other remedies creates a necessary and inescapable inference that those remedies are exclusive.

In *Porter*, the Court determined the express provision of certain remedies in the EPCA did not create a necessary and inescapable inference limiting courts’ authority to order unenumerated equitable remedies. 328 U.S. at 402. In addition to general equity jurisdiction, the EPCA provided for criminal, civil, and administrative remedies. Specifically, individuals faced criminal fines and imprisonment for violations of the Act. EPCA, § 205(b), 56 Stat. 23, 33.

Individuals injured by a violation of the act could file a civil suit seeking treble damages plus attorneys’ fees. *Id.* § 205(e), 56 Stat. at 34. If an individual was

the courts went on to determine disgorgement was not appropriate under the facts of the particular cases before them. *Richard*, 355 F.3d at 354–55; *Carson*, 52 F.3d at 1181–82.

prevented from bringing a civil suit for various reasons, the Administrator of the Office of Price Administration (“Administrator”) could sue for damages on behalf of the United States. *Id.* Finally, the Administrator had authority to suspend a violator’s license. *Id.* § 205(f)(2), 56 Stat. at 35. Despite these express remedies, the Court in *Porter* concluded the grant of general equity jurisdiction in the EPCA was not restricted. *Porter*, 328 U.S. at 402.

The express remedies provided in the FDCA are similar to those available under the EPCA. In addition to general equity jurisdiction, the FDCA explicitly provides for criminal, civil, and administrative remedies. *See* 21 U.S.C. § 333 (providing for criminal fines and imprisonment and civil monetary penalties); *id.* § 360h(b) & (e) (authorizing Secretary of Health and Human Services (“Secretary”) to order recall, repair, replacement, or refund of purchase price for medical devices); *id.* § 350a(e)(1)(B) (authorizing Secretary to recall adulterated or misbranded infant formula); *id.* § 360pp(a) & (b) (granting district courts equity jurisdiction and providing for civil monetary penalties for violation of statutory provisions relating to electronic products). These remedies are no more expansive or comprehensive than those found in the EPCA. Seizure is the only express remedy provided for in the FDCA that was not also authorized by the EPCA. *Id.* § 334. This single additional remedy, however, does not create a necessary and inescapable inference that Congress intended to exclude all other remedies.

Amicus further argues the specific authorization of restitution for certain medical devices in one provision of the FDCA shows Congress did not intend to allow disgorgement under another provision of the Act. The FDCA permits the Secretary to order the manufacturer, importer, or distributor of a medical device found in violation of the Act to refund the purchase price of the device to customers. *Id.* § 360h(b)(2)(C). Before ordering a refund, the Secretary must determine that the device presents an unreasonable risk of substantial harm to the public health; there are reasonable grounds to believe the device is defective; the defect was caused by the manufacturer, importer, distributor, or retailer; and other remedies are inadequate to eliminate the risk posed by the device. *Id.* § 360h(b)(1)(A). Amicus contends the detailed showing required to permit restitution is inconsistent with the view that Congress intended to provide for the similar remedy of disgorgement upon a mere showing of a violation of the Act.

This argument is unpersuasive. Section 360h describes only the Secretary's powers in administering the Act. The section says nothing about remedies that may be ordered by courts. We decline to read the FDCA's grant of expanded administrative powers as a diminishment of the federal courts' judicial powers under a grant of general equity jurisdiction. *See Porter*, 328 U.S. at 401–02. This reading is especially unwarranted in light of § 360h(d), which specifically provides that “[c]ompliance with an [administrative refund order] shall not relieve any person from liability under Federal or State law.” 21 U.S.C. § 360h(d).

Finally, Rx Depot argues the legislative history of the FDCA, which indicates that Congress intended seizure to be the harshest remedy available under the Act, precludes disgorgement. We are not convinced, however, that seizure is harsher than disgorgement in all circumstances. *See United States v. Universal Mgmt. Servs., Inc.*, 191 F.3d 750, 762 (6th Cir. 1999) (concluding restitution is not necessarily harsher than seizure). Procedurally, the seizure remedy permitted under the FDCA is arguably harsher than disgorgement. The FDCA permits administrative seizure on the basis of an *ex parte* showing of reasonable belief. 21 U.S.C. § 344(g). Disgorgement, on the other hand, is only permitted after a party is found by a court to be in violation of the Act and only at the court's discretion. Additionally, seizure is not necessarily harsher than disgorgement in terms of monetary loss to a company. Seizure of a company's inventory deprives the company of both capital investment and potential profit, whereas disgorgement only deprives a company of its profits. Although court-ordered disgorgement over an extended period of time may operate as a harsher remedy than a one-time seizure, the opposite is likely true for disgorgement ordered over a shorter time period. Thus, even if Congress intended seizure to be the harshest remedy available under the statute, it does not follow that Congress necessarily and inescapably intended to preclude disgorgement in all circumstances.

Because the FDCA does not contain a clear legislative command or compel a necessary and inescapable inference precluding disgorgement, an order of

disgorgement is permitted if it furthers the purposes of the FDCA. *See Porter*, 328 U.S. at 400; *Atchison*, 732 F.2d at 1507. The FDCA's primary purpose is to protect the public health. *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969). To be sure, the public health is protected not only by halting current violations of the Act, but also by deterring future violations. Disgorgement, which deprives wrongdoers of their ill-gotten gains, deters violations of the law by making illegal activity unprofitable. *SEC v. Fischbach Corp.*, 133 F.3d 170, 175 (2d Cir. 1997). As the Court noted in *Porter*, "[f]uture compliance may be more definitely assured if one is compelled to restore one's illegal gains." 328 U.S. at 400. Therefore, disgorgement furthers the purposes of the FDCA.

In sum, the FDCA invokes courts' general equity jurisdiction by authorizing courts "to restrain violations" of the Act. This broad grant of equity jurisdiction is not restricted by the text of the statute, its express provision of certain legal and administrative remedies, or its legislative history. Moreover, disgorgement furthers the purposes of the FDCA by deterring future violations of the Act which may put the public health and safety at risk. Therefore, according to the analysis established in *Porter* and *Mitchell*, we conclude disgorgement is permitted under the FDCA in appropriate cases.⁶

⁶Because the district court determined disgorgement was not available under the FDCA, it did not examine whether there were any ill-gotten gains to be disgorged or whether disgorgement was appropriate under the facts of this case.

Our determination that disgorgement is authorized by the FDCA is supported by decisions in several other circuits. Although we are the first circuit to address disgorgement under the FDCA, two circuits have held recently that restitution is authorized by the Act. These decisions, and the analysis employed by the courts in reaching them, substantiate our reasoning here.

In *Universal Management*, the Sixth Circuit upheld an order of restitution requiring a party who sold adulterated medical devices to provide refunds to its customers. 191 F.3d at 762. The court relied on *Porter* and *Mitchell* in refusing to interpret the FDCA as limiting the equitable jurisdiction of federal courts because it found no clear congressional intent to impose such a limit. *Id.* at 761–62. The court acknowledged there was some evidence of congressional intent that seizure should be the harshest remedy available under the Act, but concluded that such concerns were far from a clear statement from Congress to exclude restitution, especially when it was not clear that restitution is harsher than seizure in all circumstances. *Id.* at 762.

The Third Circuit similarly upheld the authority of courts to order restitution under the FDCA in a case involving misbranding of and failure to obtain FDA approval for dietary supplements and skin cream purported to prevent and treat cancer. *United States v. Lane Labs-USA Inc.*, 427 F.3d 219, 220 (3d

Therefore, we remand for the district court to address this issue in the first instance. See *R. Eric Peterson Constr. Co. v. Quintek, Inc. (In re R. Eric Peterson Constr. Co.)*, 951 F.2d 1175, 1182 (10th Cir. 1991).

Cir. 2005). Applying *Porter* and *Mitchell*, the court determined that a district court sitting in equity may order restitution unless the statute clearly limits the court's equitable jurisdiction or restitution does not further the purposes of the statute. *Id.* at 225. The court found no evidence in the FDCA limiting equity jurisdiction. *Id.* at 226. Moreover, the court determined restitution furthered the purposes of the statute because it protected the financial interests of consumers and deterred individuals from violating the Act. *Id.* at 227, 229. The court also distinguished *Meghrig* and *Philip Morris*. Regarding *Meghrig*, the court noted that the Supreme Court's decision rested on explicit language in RCRA and the Act's elaborate remedial scheme, neither of which are present in the FDCA. *Id.* at 231–32. The court also observed that, unlike the case before it, *Meghrig* did not involve an enforcement action by the government in which equitable powers are broader and more flexible. *Id.* at 231. Finally, the court noted that the “restitution” of past cleanup costs sought in *Meghrig* resembled traditional damages, and thus was different than the restitution sought under the FDCA, which was directly traceable to the plaintiff's illegal conduct and the harm it caused consumers. *Id.* The court distinguished *Philip Morris* by observing that the grant of equity jurisdiction in RICO is much narrower than that in the FDCA. *Id.* at 233. Specifically, the court noted, RICO expressly enumerates specific remedies, all of which are aimed at making it difficult or impossible to violate the Act in the future. *Id.* The FDCA, on the other hand, contains no such list. *Id.*

The only other circuit to address restitution under the FDCA is the Ninth Circuit. In 1956, the court held that restitution is not available under the FDCA in *United States v. Parkinson*. 240 F.2d 918, 922 (9th Cir. 1956). The court’s decision was based on the statute’s failure to explicitly grant courts authority to order restitution. *Id.* The court explained, “[t]he use of the extraordinary remedies of equity in governmental litigation should never be permitted by the courts unless clearly authorized by the statute in express terms.” *Id.* The court distinguished *Porter* by noting that the EPCA was enacted in wartime and contained explicit language, specifically the term “other orders,” authorizing the use of remedies not enumerated in the statute. *Id.* at 920 & n.6. The Ninth Circuit’s rationale in *Parkinson*, however, was subsequently rejected by the Supreme Court in *Mitchell*. In *Mitchell*, the Court reaffirmed *Porter* in holding equitable remedies need not be expressly authorized by a statute; rather, a grant of general equity jurisdiction is sufficient to enable a court to exercise all traditional equitable powers absent explicit or implicit evidence to the contrary. *Mitchell*, 361 U.S. at 290–292. Moreover, the Court noted “the applicability of this principle is not to be denied, either because the Court [in *Porter*] considered a wartime statute, or because, having set forth the governing inquiry, it went on to find in the language of the statute affirmative confirmation of the power to order reimbursement.” *Id.* at 291. Because *Parkinson*’s reasoning was later rejected by

Mitchell, it is not persuasive. *See Lane Labs*, 427 F.3d at 233–34 (rejecting reasoning of *Parkinson*).

IV. Conclusion

For the foregoing reasons, this court **REVERSES** the district court’s denial of disgorgement and **REMANDS** the matter for further proceedings not inconsistent with this opinion.

United States Court of Appeals for the Tenth Circuit
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Elisabeth A. Shumaker
Clerk of Court

Douglas E. Cressler
Chief Deputy Clerk

April 18, 2006

Mr. Phil Lombardi
Clerk
United States District Court for the N. District of Oklahoma
333 W. Fourth Street
Room 411 United States Courthouse
Tulsa, OK 74103

Re: 05-5003, United States v. RX Depot, Inc.
Dist/Ag docket: CV-03-616-EA(M),

Dear Mr. Lombardi:

Enclosed are a certified copy of the judgment and a copy of the opinion filed in this case which are issued as the mandate of this court. See Fed. R. App. P. 41(a). Please file it in records of your court or agency. The parties were provided a copy of the decision previously.

Please contact this office if you have questions.

Sincerely,

Elisabeth A. Shumaker
Clerk, Court of Appeals

By: *Opal A. Carter*
Deputy Clerk

clk:oac

cc: Alan Phelps
Gerald Kell
Cathryn McClanahan
Mark Reiling Freeman
Scott R. McIntosh
Fred E. Stoops Sr.
Diane Hinkle
Gary L. Richardson
Daniel J. Popeo
Richard A. Samp

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Phil Lombardi, Clerk
U.S. DISTRICT COURT